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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,524	07/16/2002	John Fisher	1781-0003	7210

7590

01/30/2004

Paul J Maginot  
Maginot Moore & Bowman  
Bank One Center/Tower Suite 3000  
111 Monument Circle  
Indianapolis, IN 46204-5130

EXAMINER
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SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/30/2004

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/070,524

Applicant(s)

FISHER ET AL.

Examiner

Bruce E Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Caldarise (5,641,323).

Caldarise teaches an orthopedic joint comprising first and second articulating components having contacting bearing surfaces. The components are metal/ceramic wherein the metal can be cobalt-chromium alloys, titanium-vanadium alloy, or stainless steel and the ceramic can be alumina, zirconia, etc. Inherently, all claimed hardness limitations are met.

Regarding claim 5, zirconia is zirconium oxide, for example.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caldarise (5,641,323) in view of Davidson (5,037,438).

Caldarise teaches the orthopedic joint as described above however is silent regarding the material of the bearing surface of least component being a surface layer. Davidson teaches an orthopedic joint wherein zirconia can be applied as a surface

layer. It would have been obvious to one having ordinary skill in the art to have substituted a component having a surface layer of zirconia as taught by Davidson for the ceramic component of Caldarise wherein the underlying material, such as a metal, can better transfer heat away from the articulating surface increasing wear or said underlying material is cheaper/easier to manufacture.

See 2:67 teaching thickness of 50-300 microns.

Regarding claim 11, it is well known in the art that articulating surfaces of orthopedic joints should have little or no surface roughness to increase wear. It would have been obvious to one having ordinary skill in the art to have done so with the device of Caldarise in view of Davidson.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caldarise (5,641,323) in Farrar (EP 0841041).

Caldarise teaches the orthopedic joint as described above however is silent regarding the surface roughness of each of the bearing surfaces. Farrar teaches the articulating surfaces of an orthopedic joint should be minimized; see 2:26-42. It would have been obvious to one having ordinary skill in the art to have minimized the surface roughness as taught by Farrar on the joint of Caldarise to "minimize wear".

### ***Answer to Arguments***

Applicant's argument filed 11/21/03 was not persuasive. Applicant does not argue that Caldarise fails to teach an orthopedic joint comprising first and second

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articulating components having contacting bearing surfaces wherein the components are metal/ceramic wherein the metal can be cobalt-chromium alloys, titanium-vanadium alloy, or stainless steel and the ceramic can be alumina, zirconia, etc. For the record, applicant also does not argue that the metal components do not inherently meet the claimed hardness limitation. What applicant argues is that Caldalise uses a 3-D printing technique to form the ceramic material. What applicant fails to understand is that Caldalise '323 teaches the 3-D printing technique as a method of forming the mold used to form one of the components and not the method of directly forming the component.

**Emphasis added.** Caldalise '323 column 3, lines 17 et seq. *"[t]he implantable articles of the invention can be manufactured by suitable casting techniques. Preferably, however, the casting molds use in the casting process are prepared through a three-dimensional (3-D) process."* Therefore, applicant's argument is not commensurate with the teachings of Caldalise '323. (Note that Caldalise 5,641,323 is the only reference used in the rejection of claims 1-8)

To merely entertain applicant's argument and assume that the ceramic component was directly formed by a 3-D printing process, the Examiner notes that applicant incorrectly incorporates a later Caldalise Patent, No. 5,788,916. Applicant states that a component made by this process would be a low density ceramic material and can not have the hardness of at least 6500 Mpa. This is unfounded. Applicant further states regarding their ceramic materials, *"exposure to high pressure results in the material having low porosity and, as a consequence, high desity"*. This was not found in the specification and too is unfounded. Applicant teaches that medical grade

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alumina has a hardness of 16,000 Mpa (see specification page 7, line 4) and argues that the alumina of Caldarise '323 has a hardness of less than 6,500 Mpa; this is absurd.

Finally, to fulfill the requirements as set forth in claim 1 only requires that the material of the bearing surface be the claimed hardness and **not** that the bearing surface itself be the claimed hardness. It is the Examiner's strong position that material characteristics are inherent to themselves.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

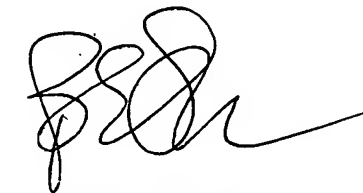
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

bes  
January 28, 2004

A handwritten signature in black ink, appearing to read 'BSN', with a long horizontal line extending to the right.

BRUCE SNOW  
PRIMARY EXAMINER